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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,906	06/27/2006	Cesar Milstein	DYC0101PUSA	7670

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EXAMINER	
SAUNDERS, DAVID A	
ART UNIT	**PAPER NUMBER**
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,906	MILSTEIN ET AL.	
	Examiner	Art Unit	
	David A. Saunders	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment of 9/7/04 has been entered. Claims 1-24 are pending and subject to restriction. Restriction is required under 35 U.S.C. 121 and 372.

RESTRICTION GROUPS

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3, 5, 17, drawn to a shed CD (sCD) antigen fingerprint/pattern.

Group II, claim(s) 2, 4, 6-16, drawn to methods of obtaining and using a (sCD) antigen fingerprint/pattern. (It is to be noted that the examiner has included claim 4 with Group II, because it positively recited "method" in line 1; it's dependency from claim 1 is considered to have not been intended. It is also to be noted that claims 15 reciting "use of " is taken to be a method claim).

Group III, claim(s) 18-24, drawn to methods of treatment using inhibitors of the production of one or more sCDs. (It is also to be noted that claim 23 reciting "use of " is taken to be a method claim).

REASONS INVENTIONS LACK UNITY

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The IPEA has found prior art that certainly anticipates one or more claims of Groups I and II (even though the IPEA did not reject claim 1, the amended form of claim 1 at this National Stage would certainly be anticipated by the prior art cited by the IPEA). Futhermore, even if the IPEA had not found prior art, the Claims of Group I are considered to be referring to a fingerprint/pattern, which is nothing more than an

intellectual construct/concept. As such, a shed CD (sCD) antigen fingerprint/pattern of Group I cannot constitute a contribution over the prior art.

The claims of Groups II and III lack a common technical feature because the claims of group III are mere reach through claims that recite no particular agent for inhibiting the production of sCDs. Furthermore, the claims of Groups II and III lack a common technical feature, because they are of different scope with respect to the number of sCD antigens involved. It is clear from claim 2 of (group II), as well as from the disclosure, that a shed CD (sCD) antigen fingerprint/pattern involves "more than one shed sCD" (claim 2, lines 2-3); on the other hand, it is clear from claims 18 and 23 (Group III) that the method of treatment can involve using an inhibitor of the production of only one sCD. Thus the number of sCDs that must be assayed, in the method of Group II, is not commensurate in scope with the number of sCDs that may have their production inhibited, in the method of group III.

ELECTION OF SPECIES

In the event that either of Groups I or II is elected, the following election of species will be required.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The numerous combinations, each having 2 of the sCD antigens contemplated by applicant (e.g. as listed at specification pages 50-159).

Applicant is required, in reply to this action, to elect a single species (a combination of 2 of the sCD antigens) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

none

The following claim(s) are generic: all of claims 1-18.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: It is impossible to determine the exact number of sCD antigens listed at pages 50-159, because numerous of the CD antigens from CD2 to CD157 are not listed as having soluble forms. If one assumes that a total of about 50 distinct sCD antigens are listed then the number of combinations of 50 sCD antigens, taken 2 at a time, would be:

$50!/2!(50-2)! = 50!/2(48!) = (50 \times 49)/2,$

which would be a burdensome number of combinations to search.

In the event that any of Groups I-III is elected, the following election of species will be required.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The numerous and diverse types of disease states disclosed at, for example, specification pages 13, 17, 22.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

none

The following claim(s) are generic: all of claims 1-24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Different search terms would be required foreach of the different disease states. A reference showing a method that obtains a sCD profile of one disease state would not suggest that the same, or indeed any, sCD profile would be obtained with another disease state.

In the event that Group III is elected, the following election of species will be required.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The numerous and diverse types of inhibiting agents that could be used in the treating method of group III. The examiner cannot even determine where applicant has listed contemplated species, other than those that constitute the subgenus of "CD specific alternative splicing inhibitors".

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claim 21, to the subgenus of "CD specific alternative splicing inhibitors".

The following claim(s) are generic: claims 18-20 and 22-24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Since one has no idea what the inhibiting agents that could be used in the treating method of group III might be, other than those belonging to the subgenus of "CD specific alternative splicing inhibitors", the search for a method of treatment with any, unspecified inhibitor would be burdensome.

From the above listings of species, it is to be noted that, if applicant elects one of Groups I or II, then a particular combination of a pair of sCD antigens and a single disease state must be elected.

From the above listings of species, it is to be noted that, if applicant elects Group III, then a particular combination of a pair of sCD antigens, a single disease state, and a single inhibitor agent must be elected.

ADVISORIES TO APPLICANT

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

CONTACTS

Any inquiry concerning this communication from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 10/1/07 DAS

David A Saunders

DAVID A. SAUNDERS
PRIMARY EXAMINER